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MEDICAL RESEARCH DATA-SHARING: THE 'PUBLIC GOOD' AND VULNERABLE GROUPS

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Abstract: One of the moral tests of governments is how they treat those in the twilight of life (the elderly). As such, it is important not only to take care of the needs of the elderly, but also to place their reality in the forefront of deliberations and actions. Now that we are in the so-called 'century of biology', we must ensure that the newly transformed and increasingly relied on biosciences not only respond to the needs of the elderly but also reflect the reality of the elderly. While many arguments can be made in support of increased data-sharing in biomedical research (and indeed within and across healthcare systems more generally), there are some persuasive age-based arguments that might serve to encourage science regulators, through both funding structures and the law, to fundamentally reshape the research environment so as to enhance its potential to achieve public goods such as improved health and more effective healthcare systems. In this paper, after noting the new research model arising from population genomics, with its intense data needs, we advance three age-based arguments, in favour of increased and improved data-sharing, and we conclude with some brief observations about how increased data-sharing might be achieved.

Keywords: aging; healthcare; biomedical research; data-sharing; human rights; values; solidarity; reciprocity; altruism

INTRODUCTION

In claiming that the moral test of governments is how they treat those who are in the dawn of life (children), the twilight of life (the elderly), and the shadows of life (the sick, needy, and handicapped),¹ Hubert Humphrey highlighted the importance not only of taking care of the needs of those in the margins, but of placing their reality in the forefront of deliberations and actions, even where they may seem not to be directly relevant. In claiming that the 21st century would be the 'century of biology',² Nobel Laureate Robert Curl anticipated the growth and transformation of the biosciences, and appreciated the increasing reliance that would be placed on them

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¹ H. Humphrey, Remarks at the Dedication of the Hubert H. Humphrey Building on 1 November 1977, Congressional Record, 4 November 1977, vol. 123, p. 37287.

² J. Rifkin, "The Biotech Century: Playing Ecological Roulette with Mother Nature's Design", *E: The Environmental Magazine*, May-June 1998, available at http://findarticles.com/p/articles/mi_m1594/is_n3_v9/ai_20581506/?tag=content;coll.

despite the risks that their outputs represent. These two concerns – needs of, and pressures created by, the vulnerable on the one hand, and the needs of, and possibilities for, the biosciences on the other – inform the central argument of this paper, which is that science regulators, through both funding structures and the law, should fundamentally reshape the research environment so as to increase and improve data-sharing amongst researchers and primary research users.

Calls abound to assess existing rules and practices with a view to fashioning a new consensus that enables research while respecting the rights and obligations of all stakeholders,³ and this paper contributes to that endeavour, taking into account ‘public goods’ and ‘vulnerable populations’. While a compelling science-based argument can be made for increased data-sharing (ie: for more ‘open science’), we draw on science only to demonstrate that research models are changing (or rather diversifying), and that new and emerging models, particularly those in the population genomics setting, demand increased and improved data-sharing if they are to achieve their promise. This insight serves as a preliminary argument to the primary argument, which is that better acknowledgement of the rights of, pressures created by, and duties toward vulnerable groups serves the overall public good, and offers an additional justification for improved data-sharing.

While any number of vulnerable groups might serve as a legitimate case study, particularly where that vulnerability stems from being at or near the end of life (eg: high risk or terminal cancer patients might illustrate the argument), we focus on the elderly. And while the elderly are *not* a homogenous group, for present purposes we assume the elderly, as an aggregated group, to be:

- seventy years-old or over;
- entering a life-stage of increasing infirmity which, in addition to potential sudden and profound health degradations, is likely to involve chronic health conditions; and
- more frequent and more cost-intensive users of healthcare services.

After briefly articulating the preliminary science-based argument for increased data-sharing, we move to our main (non-science-based) argument. We advance a rights claim, a systems claim, and an ethical claim in support of the position that the elderly (as one of a number of vulnerable groups), through their rights-holding, healthcare system usage, and research participation, justify increased data-sharing.⁴ We conclude with some brief observations about how increased data-sharing might be achieved, but we must stipulate that we do not intend to offer a fully-designed legal regime; such is beyond the scope of the paper.

PRELIMINARY ARGUMENT: DATA NEEDS IN NEW SCIENCE MODELS

Now well into the 21st century, we can see, as Curl predicted, that the biosciences are rising in scientific and social significance. Indeed, the biosciences themselves are transforming with respect to how they are conceptualised and studied. Frequently

³ Representations at the International Data Sharing Conference, hosted by HeLEX, in Oxford, on 20-22 September 2010, and those directed at the Oxford Call to Action, which is emerging therefrom. See <http://www.publichealth.ox.ac.uk/helex/events/data-sharing-international-conference-1>.

⁴ We emphasise that this is not a defence of the taking or using of medical data from tissue or from healthcare records, but rather a demand for the improved use of data already obtained presumably through legitimate processes.

shaped by computational and engineering metaphors, they are increasingly cellular, longitudinal, fragmented, and data-reliant. The new research model bears the following features:⁵

- It is increasingly based on genomic investigations, and on whole-genome research and thus has a built-in reliance on metadata and massive sample sizes.⁶ Thus, it is dependent on newly developed and quickly evolving technologies in the bioinformatics and related fields, particularly high-throughput sequencing technologies with high computational capacities.⁷
- It is increasingly interdisciplinary and segmented. Its scale and complexity (ie: testing gene-to-gene and genetic-environmental factors in the development, progress, and possible treatment of diseases) means that research is often collaborative and reliant on collections of individuals with different skills and backgrounds and highly differentiated and sometimes narrow tasks (eg: principal investigator, recruitment or sample collection team, sequencing team, data analysis team, including informaticians and statisticians, data repository curators, etc.).⁸ This diffusion of responsibilities across institutions, both academic and commercial, and across national borders, means that data must be shared within projects and beyond the collecting team. Some tissue (and associated data) is collected and retained specifically for distribution to secondary researchers of diverse background and interest, a practice which is widely considered to be of significant scientific, healthcare and commercial value.⁹
- It often has little expectation of immediate outcomes capable of translation into clinical practices. Population-based genomic research in the form of biobanks, both ‘primary’ and ‘secondary’,¹⁰ is an example of this, and they are

⁵ For more on the new model, see House of Lords Science & Technology Committee, *2nd Report of Session 2008–09: Genomic Medicine* (London: Stationary Office, 2009), available at <http://www.publications.parliament.uk/pa/ld200809/ldselect/ldsctech/107/107i.pdf>.

⁶ Digital Archiving Consultancy et al., *Large-Scale Data Sharing in the Life Sciences: Data Standards, Incentives, Barriers and Funding Models* (2005), available at http://dtl.unimelb.edu.au/R/USXD3V19SHBSCYV36CNMIT6TYTHGK7UQDYYD1PLMCMULA189CE-00409?func=dbin-jump-full&object_id=263978&pds_handle=GUEST.

⁷ C. Shaffer, “Next-Generation Sequencing Outpaces Expectations” (2007) 25 *Nature Biotech* 149.

⁸ M. Gibbons et al., *The New Production of Knowledge: The Dynamics of Science and Research in Contemporary Societies* (London: Sage, 1994), J. Ziman, *Real Science: What It Is and What It Means* (Cambridge: CUP, 2000), others.

⁹ J. Kaiser, “Population Databases Boom: From Iceland to the US” (2002) 298 *Science* 1158-1161.

¹⁰ Primary biobanks generate new data collections for defined purposes. An example includes the UK Biobank, a repository of biological samples and health data from some 500,000 volunteers between the ages of 40-69 aimed at helping scientists develop better methods of prevention, diagnosis, and treatment for combating the conditions of old age, and to thereby improve the health of future generations: see <http://www.ukbiobank.ac.uk/>. Secondary biobanks aggregate and manage samples and data originated by others for specific purposes but which now may be valuable for other research purposes. An example is the UK DNA Banking Network which aims to provide data to genome-wide association studies which seek to identify multiple loci which contribute to genetic risk for given diseases: see <http://www.dna-network.ac.uk/>, and see M. Yuille et al., “The UK DNA Banking Network: A ‘Fair Access’ Biobank” (2010) 11 *Cell Tissue Bank* 241-251.

experiencing a boom.¹¹ Such biobanks are: (1) collective (reliant on mass participation); (2) inclusive (include healthy people and even children); (3) prospective (enduring for a long time into the future and ideally beyond the life of original participants); and (4) purposively indeterminate (not tied to a single objective).¹²

Ultimately, modern research exhibits a complexity of scientific questions, of methods for answering them, and of answers being offered, and a complexity of research organisation (which sometimes has a complete separation of resource and/or data collection and data deployment, or analysis and interpretation).¹³

In light of this universally-experienced complexity, one might have expected a common method of data-sharing to emerge. However, there is no common method or common approach. Most data-sharing occurs on an ad hoc or project-grounded basis, and much of it is reliant on personal relationships.¹⁴ Additionally, there is no common (cross-jurisdictional) instruction on data-sharing. It is governed, to the extent that it is governed at all, by professional standards or practices, research funder demands, and non-binding international declarations, and for those who do not require public funds (or public partnerships), there are no binding guidelines whatsoever. In short, despite the greater and growing demand for readily available data, and the widespread recognition that data-sharing, as a matter of course, accelerates the progress of research and its translation into socially useful products or practices,¹⁵ efficient, effective, and systematised data-sharing has not (yet) become the norm.

Campbell et al. conducted a survey of geneticists in the USA which indicated that, in the previous three years, 47% of respondents had denied at least one request for data, information or material on published results.¹⁶ Bovenberg conducted a web-survey of 118 human geneticists in 15 countries in which 51% of respondents indicated that they did not grant access to their databases to non-commercial entities.¹⁷ The Royal Netherlands Academy of Sciences conducted a web-survey on Dutch population cohorts and patient databases which indicated that 1.5% of respondents made their anonymised data publicly available, 73.3% permitted access on special terms and conditions, and 15% did not give access.¹⁸ Blumenthal et al.

¹¹ B. Elger & A. Caplan, "Consent and Anonymization in Research Involving Biobanks" (2006) 7 EMBO Reports 661-666.

¹² For more on them, see G. Williams, "Bioethics and Large-Scale Biobanking: Individualistic Ethics and Collective Projects" (2005) 1 Genomics Society Policy 50-66, and S. Harmon, "Semantic, Pedantic or Paradigm Shift? Recruitment, Retention and Property in Modern Population Biobanking" (2008) 16 European J Health Law 27-43.

¹³ The problems that this reality poses for consent have been discussed in S. Harmon, *ibid.* For an attempt to address some of these issues, see M. Angrst, "Eyes Wide Open: The Personal Genome Project, Citizen Science and Veracity in Informed Consent" (2009) 6 Personalised Medicine 691-699.

¹⁴ J. Kaye et al., "Data Sharing in Genomics: Reshaping Scientific Practice" (2009) 10 Nature Rev Gen 331-335.

¹⁵ J. Walker et al., "The Value Of Health Care Information Exchange And Interoperability" (2005), available at http://www.partners.org/cird/pdfs/CITL_HIEI_Report.pdf, P. Arzberger et al., "Promoting Access to Public Research Data for Scientific, Economic and Social Development" (2004) 3 Data Sci J 135-152, H. Piwowar et al., "Sharing Detailed Research Data Is Associated with Increased Citation Rate" (2007) 2 PLoS ONE e308, P. Schofield et al., "Post-Publication Sharing of Data and Tools" (2009) 461 Nature 171-173.

¹⁶ E. Campbell et al., "Data Withholding in Academic Genetics: Evidence from a National Survey" (2002) 287 JAMA 473-480.

¹⁷ J. Bovenberg, "Blood, Sweat and Grants: 'Honest Jim' and the European Database-Right" (2005) 1 Genomics Society Policy 1-28.

¹⁸ *Ibid.*

conducted a survey of university-based life science researchers in the US which found that data withholding is common, takes multiple forms, is influenced by a range of investigator characteristics, and varies by field.¹⁹

More recent evidence suggests that this situation has not dramatically improved.²⁰ A Joint Statement issued by an international collection of funders further confirms it:

In some research fields ... data sharing is well-established and has accelerated the progress of research and its application for the public good. In public health research, however ... the sharing of data is not yet the norm, even within the scientific community.²¹

All told, the prevailing research environment hinders effective data- and knowledge-sharing and therefore the more timely delivery of useful products and practices,²² and so cannot be considered fit-for-purpose. One aspect of that sub-optimal environment is the regulatory milieu; research positively wallows in instruction, which exhibits a volume and complexity that naturally dissuades sharing. With respect to genomic medicine, Andrew Morris, Chairman of the Generation Scotland Scientific Committee, reported the following in 2008:

The Department of Health guidance suggests that this domain [the use of health records for genomic research] is affected by 43 relevant pieces of legislation. There were 12 sets of relevant standards and 8 professional codes of conduct. What this has bred is a culture of caution, confusion, uncertainty and inconsistency.²³

It has also been claimed that:

... [T]here is evidence that UK health research activities are being seriously undermined by an overly complex regulatory and governance environment. ... New regulatory bodies and checks have been introduced with good intentions, but the sum effect is a fragmented process characterised by multiple layers of bureaucracy, uncertainty in the interpretation of individual legislation and guidance, a lack of trust within the system, and duplication and overlap in responsibilities.²⁴

¹⁹ D. Blumenthal et al., “Data Withholding in Genetics and the Other Life Sciences: Prevalences and Predictors” (2006) 81 *Academic Medicine* 137-145.

²⁰ See Wellcome Trust Press Release, “Global Funding Agencies Commit to Enhancing Access to Research Data to Improve Public Health”, 10 January 2011, available at <http://www.wellcome.ac.uk/News/Media-office/Press-releases/2011/WTX064132.htm>.

²¹ Research Funders, *Sharing Research Data to Improve Public Health: Joint Statement of Purpose*, January 2011, available at <http://www.wellcome.ac.uk/About-us/Policy/Spotlight-issues/Data-sharing/Public-health-and-epidemiology/WTDV030690.htm>.

²² So claimed by M. Yuille in comments posted at <http://helexoxford.com/content/oxford-statement-data-sharing> in relation to the International Data Sharing Conference, hosted by HeLEX, in Oxford, on 20-22 September 2010, and so noted in Academy of Medical Sciences, *A New Pathway for the Regulation and Governance of Health Research* (London: AMS, 2011).

²³ House of Lords Science and Technology Committee, *supra*, note 5, at para. 6.15.

²⁴ AMS, *supra*, note 22, at 2 and 3. A position confirmed by the HFEA, HTA and MHRA when they conceded the need for their Interim UK Regulatory Route Map for Stem Cell Research & Manufacture, available at <http://www.keele.ac.uk/research/istm/HTA/Governance/Interim%20UKSC%20routemap.pdf>.

The overlapping regulatory *systems* which prevail erect sometimes vague and often conflicting demands and standards. This, together with the many actors and interests at play, makes confidently operating (and data-sharing) within the research environment very difficult. Despite these hurdles, a number of recent research projects have adopted open data-sharing practices as a means of generating impact (eg: HapMap Project,²⁵ 1000 Genome Project,²⁶ Database of Genotypes and Phenotypes,²⁷ Genetic Association Information Network,²⁸ Wellcome Trust Case Control Consortium,²⁹ and Nottingham Arabidopsis Stock Centre³⁰), but these examples are singular and pragmatic. In any event, all of this supports the argument that the new research model demands new and more harmonised/standardised approaches to increased and more rapid data-sharing, but, as noted above, arguments in support of data-sharing are not limited to the scientific.

PRIMARY ARGUMENT: CONSIDERATION OF THE VULNERABLE CREATES AN IMPERATIVE FOR DATA-SHARING

Our primary argument, very simply, is that the unfolding demographic shift that society is experiencing favours increased and improved data-sharing in bioscience research. A serious recognition of the realities of an aging population could and should lead to changes in scientific practices, including changes to data-sharing. We have been called upon to pay much more attention to the needs, contributions, and rights of elderly people,³¹ and we must therefore reconsider their role as (1) health rights holders (ie: what is owed to the elderly), (2) as healthcare recipients (ie: the

²⁵ The HapMap Project (2002-2007) was a multi-country collaboration among scientists and agencies from Canada, China, Japan, Nigeria, the United Kingdom and the United States aimed at identifying and cataloguing human genetic similarities and differences and thereby discovering genes that affect health, disease, and individual responses to medicines and environmental factors. See <http://hapmap.ncbi.nlm.nih.gov/thehapmap.html.en>.

²⁶ The 1000 Genome Project (2007-) is a human genome reference project aimed at finding the most genetic variants that have frequencies of at least 1% in the populations studied. See <http://www.1000genomes.org/about>.

²⁷ The dbGaP is a repository for archiving and distributing the study documents, phenotypic data, genetic data, and statistical results of studies that have investigated the interaction of genotype and phenotype. Such studies include genome-wide association (GWA) studies, medical sequencing, molecular diagnostic assays, as well as association between genotype and non-clinical traits. See <http://www.ncbi.nlm.nih.gov/projects/gap/cgi-bin/about.html>.

²⁸ GAIN is a public-private partnership which invites data from investigators of existing case-control or trio (parent-offspring) studies, and it supports GWA studies designed to identify the relation between specific DNA variation and particular common diseases. Data is held in a database at the National Library of Medicine at the NIH for further use by other researchers. GAIN gives data producers a six month publishing lead over competitors. Requests for access are considered by an NIH Data Access Committee. See <http://www.genome.gov/19518664>.

²⁹ The WTCCC is a collaboration of UK-based geneticists analysing thousands of DNA samples from a range of specific GWA studies aimed at identifying common genetic variations for different diseases. While some data is available on the internet, genotypic and phenotypic data is obtained by application to the Consortium Data Access Committee. See <http://www.wtccc.org.uk/>.

³⁰ NASC offers a transcriptomics service to process samples and RNA with Affymetrix gene chips. It makes all donated data publicly available after a confidentiality period of 3, 6, or 12 months, depending in what donors/customers choose; the length of the confidentiality period is linked to the priority that donors demand for analysis service (ie: a request for quick processing results in the provision of a shorter confidentiality period). See <http://affymetrix.arabidopsis.info/>.

³¹ An avalanche of policy documents on this exists, but see T. Nilström & R. Ohlsson, "Should Health Care be Rationed by Age?" (1995) 23 Scan J Social Med 81-84.

health pressures the elderly generate), and (3) as research participants (ie: how the elderly are engaged with medical research). While each of these perspectives have a moral element or character, we classify them as a rights argument (Argument 1), a systemic argument (Argument 2), and an ethical argument (Argument 3).

Argument 1: Elder Rights and Health Rights Demand Healthcare Solutions

The first age-based argument is a rights-based argument (and a cognizance of these rights should be retained throughout). Broadly, it is as follows: We have worked very hard over the last 60+ years to create a ‘rights society’;³² indeed the rights paradigm is becoming the dominant socio-legal paradigm around the world. Certain human rights, some of them directly relating to health and/or to the elderly, demand that we do more to support the health of the elderly. One way to better operationalise these rights is to better support data-sharing.

Everyone, including the elderly, has a right to the highest attainable standard of physical and mental health, and the right to a standard of living adequate for their health and needs, including, *inter alia*, medical care and social services. This so-called ‘right to health’ is contained in a plethora of international instruments, some of them legally binding, including the Universal Declaration of Human Rights (1948) (UDHR),³³ the WHO Constitution (1948),³⁴ the International Covenant on Economic, Social and Cultural Rights (1966) (ICESCR),³⁵ the International Convention on the Elimination of All Forms of Racial Discrimination (1966),³⁶ the Declaration of Alma-Ata (1978),³⁷ the Ottawa Charter for Health Promotion (1986),³⁸ the Convention on the Rights of the Child (1990),³⁹ and the Bangkok Charter for Health Promotion in a Globalised World (2005).⁴⁰

While sometimes viewed as an aspirational rather than an enforceable right, the ‘right to health’ is increasingly seen as essential to achieving healthy and equitable societies. It has informed health policy reforms.⁴¹ It has been relied on in judicial orders for the restructure of domestic health systems.⁴² And, in a study of 73 access-to-medicine cases from low and middle income countries, it has been shown that the ‘right to health’, as articulated in these instruments and *sometimes* transposed into domestic constitutional law, has consistently been relied on by courts when extending medical services to claimants (and this ‘right to health’ has been variously linked to

³² We are generally trying to forge a society shaped by positive rights supported by legal protections and processes that are available to all, including scientists, the elderly, and others. However, as a result of individual and collective practices, that society remains, in many ways, aspirational.

³³ UN General Assembly Res. 217A (III), UN GAOR, 3d Sess., UN Doc. A/810, 1948, Article 25.

³⁴ Available at <http://apps.who.int/gb/bd/PDF/bd47/EN/constitution-en.pdf>.

³⁵ 993 UNTS 3, Articles 9 and 12 and General Comment 3.

³⁶ 660 UNTS 195.

³⁷ WHO. Available at http://www.who.int/hpr/NPH/docs/declaration_almaata.pdf.

³⁸ WHO. Available at <http://www.who.int/healthpromotion/conferences/previous/ottawa/en/>.

³⁹ 1577 UNTS 44.

⁴⁰ WHO. Available at http://www.who.int/healthpromotion/conferences/6gchp/hpr_050829_%20BCHP.pdf.

⁴¹ Uganda Ministry of Health, *Review of the HSSPII in Relation to Human Rights and Gender as Part of the Third-Term Review for the Health Sector*, Second Draft (Kampala: Ministry of Health, 2008).

⁴² *Tutela Decision*, T-760/2008, 31 July 2008, Colombian Constitutional Court.

the right to life, to dignity, and to physical integrity).⁴³

Importantly, the elderly are entitled to their ‘right to health’ in an equitable and non-discriminatory manner. Most international human rights instruments emphasise equality and stipulate that *all* rights are to be enjoyed equally by *all* groups; the elderly are not infrequently specifically identified through prohibitions against age discrimination, and this prohibition is reiterated with respect to enumerated health provisions.⁴⁴ In Europe, this equality is established by the Revised European Social Charter (1996),⁴⁵ by Protocol 11 (1998) of the European Convention on Human Rights (1950),⁴⁶ and by the EU Charter of Fundamental Rights (2000),⁴⁷ and both the UN and the WHO have condemned ‘ageism’, including ageism in healthcare provision.⁴⁸

In addition to equality and the equal protection of this ‘right to health’, the elderly have a number of other rights specifically directed at them and aimed at ensuring that they retain dignity and autonomy despite possible infirmity and cognitive diminishment. For example, they have:

- the right to special protection in old age, including that related to social security, food, specialised medical care, and social and vocational engagement;⁴⁹
- the right to special protection consistent with their needs;⁵⁰
- the right to dignity and independence;⁵¹ and
- the right to expect public and private services designed to allow them to remain active members of society for as long as possible.⁵²

The UN has also articulated a number of principles with explicit health implications, including those of ‘independence’, ‘participation’, and ‘care’.⁵³ With respect to medical research more specifically, the UN Human Rights Committee has declared that special protection and special attention is needed with respect to consent

⁴³ H. Hogerzeil et al., “Is Access to Essential Medicines as Part of the Fulfilment of the Right to Health Enforceable Through the Courts?” (2006) 368 *Lancet* 305-311.

⁴⁴ See for example, Article 9 of the ICESCR (1966), which states that every person should be granted access to social security, and Article 3 of the European Convention on Biomedicine (1998) and Article 34 of the EU Charter of Fundamental Rights (2000), which emphasise the right to equitable access to healthcare of appropriate quality without discrimination.

⁴⁵ See Part I, Article E, available at <http://conventions.coe.int/treaty/en/treaties/html/163.htm>.

⁴⁶ See Article 14, available at http://www.echr.coe.int/NR/rdonlyres/D5CC24A7-DC13-4318-B457-5C9014916D7A/0/ENG_CONV.pdf.

⁴⁷ See Article 21, available at http://www.europarl.europa.eu/charter/pdf/text_en.pdf.

⁴⁸ Note the UN International Year of Older Persons 1999, and see A. Kalache & I. Keller, “The WHO Perspective on Active Ageing” (1999) 6 *Global Health Promo* 20-23.

⁴⁹ Articles 9 and 17 of the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights (1989), OASTS 69, available at <http://www.oas.org/juridico/english/treaties/a-52.html>.

⁵⁰ Article 18 of the African Charter on Human and Peoples’ Rights (1981), 21 *ILM* 58.

⁵¹ Article 25 of the EU Charter of Fundamental Rights (2000).

⁵² Articles 12 and 23 of the Revised European Social Charter (1996).

⁵³ UN Principles for Older Persons, General Assembly Res. 46/91, UN GAOR, 46th Sess., 74th Plen. Meeting, Annex 1, UN Doc A/RES/46/91 (1991). See also UN, “Report of the Second World Assembly on Ageing”, UN Doc. A/CONF.197/9, 2002.

procedures involving the elderly, particularly where their capacity is reduced.⁵⁴

In combination with the legal and social entitlements that Europeans generally enjoy (and expect),⁵⁵ the effect of these rights is that the elderly have much higher aspirations than previous generations for reaching old age and for sustaining health in old age.⁵⁶ In other words, the increased prospects that our rights society has generated has simultaneously generated greater demands; people do not just want longer life, they want an increased number of healthy life years.⁵⁷ They want capacity and productivity. They want ‘quality of life’ in their old age. In the absence of robust health (entailing independence and productivity), they want their extended life to nonetheless be a life of dignity and respect.⁵⁸ They want a ‘life worth living’, even if it is not the life they previously had, or had envisioned for themselves. As a result of these wants, which are not limited to existing seniors but are also held by the ‘anticipatory elderly’, people are demanding, and will continue to demand, more of their declining years, and so they are demanding, and will continue to demand, more of the health system and associated health research and its resultant new technologies and practices,⁵⁹ and they are often pursuing these demands through rights claims.

Of course, the reality is that many of the above-noted rights are ‘progressive’ insofar as states are expected to move towards an ideal and to make (difficult) decisions about how and in what order to operationalise programmes aimed at realising them. This operationalisation lag means that health systems will not (and need not) be comprehensive, or even optimal. States are not held to standards of perfection, and there is no enforceable expectation that health systems will be the primary policy or funding priority of governments. In real terms, this means that healthcare interventions will be rationed and health research will be patchy (ie: it will seek solutions for some conditions at the expense of others and it will not necessarily be funded in a strategic manner). However, the existence of these overlapping rights and the welter of reiterations and efforts to embed and realise them means that we should (and must) take steps whenever possible to facilitate the dissemination of knowledge so that more patients, including elderly patients, might benefit more quickly from research and its uptake in health systems, particularly when those elderly patients have contributed to that research in a direct way. Even if existing individual elders do not materially benefit from that research, data-sharing will allow us (as a research community) to better and more quickly realise the ‘right to health’ for all.⁶⁰

⁵⁴ UN Human Rights Committee, *General Comment 7: Torture or Cruel, Inhuman or Degrading Treatment or Punishment*, UN Doc HRI/GEN/1/Rev. 1 (1994).

⁵⁵ Including strong mobility rights, increasing levels of education, widely available information about technological capabilities and geographic inequalities, and rising desires for varied, self-actualising leisure opportunities.

⁵⁶ E. Rynning, “The Ageing Populations of Europe: Implications for Health Systems and Patients’ Rights” (2008) 15 *Euro J Health Law* 297-306.

⁵⁷ We recognise that desires, even those indirectly fuelled by rights, do not automatically entitle, much less grant, individuals the right to have those desires satisfied, but, we contend, a welfare-based rights society would and should endeavour, as far as possible, to deliver on the desires that our rights instruments feed.

⁵⁸ With respect to long life, some argue that there is no evidence that humans have reached the limit of life expectancy: J. Oeppen & J. Vaupel, “Demography: Broken Limits to Life Expectancy” (2002) 296 *Science* 1029-1031.

⁵⁹ For evidence of the hope being placed in new technologies, see European Commission, *Together for Health: A Strategic Approach for the EU 2008-2013* (Luxembourg: EU Publications Office, 2007).

⁶⁰ Increased sharing of research and health data is also important for measuring how countries

In short, the elderly are important rights-holders; they are not only holders of the usual and universally shared rights, but also holders of rights specifically designed for them as vulnerable individuals. In other words, while the elderly are a large and growing collection of people, they are a vulnerable group (akin to a minority) whose voice needs to be heard and taken into account (ie: their desires need to be realised through both politics and the law).⁶¹ And their desires include increased activity and actualisation in their late-life years. If health-related rights and elder rights are to be realised, better use must be made of research funding and outputs. This supports the contention that increased and improved data-sharing is important.

Argument 2: Aging Populations Place Greater Demands on Healthcare Systems

The second age-based argument shifts from the elderly as rights-holders to the elderly as change-prompters and (recidivist) users of healthcare systems. It goes as follows: The inexorable growth of the elderly demographic is putting ever-increasing pressures on healthcare systems. To avoid system-collapse, we must design greater efficiencies in health research and the translation of new knowledge into practices and products useful to healthcare systems. One way of doing so is to increase data-sharing.

Most developed countries, including European countries, are in a period of critical demographic shift. From a beginning-of-life perspective, countries where women have been mainstreamed into the paid workforce and have therefore postponed childbearing have experienced dropping birth rates. In Europe, women give birth to approximately 1.52 children; less than is needed to maintain the population in the absence of inclusive immigration policies.⁶² The result of this is that populations are expected to decrease from now to 2050 and beyond.⁶³ In parallel with this beginning-of-life trend, life expectancy has been rising for the last 50+ years. Thus, from an end-of-life perspective, death has been ‘postponed’ with the result that populations are aging. The World Health Organisation (WHO) estimates that the 60+ age group is the fastest growing age group in the world.⁶⁴ These parallel demographic trends are causing, and will continue to cause, profound social, political, ethical, economic, and legal consequences.⁶⁵

From a health and healthcare perspective, these trends (ie: declining population growth on the one hand, and longer life expectancy and aging populations on the other) will have dramatic consequences. It is anticipated that health and social programmes, and healthcare systems more generally, will be seriously burdened.⁶⁶

are performing with respect to health; current data practices hinder investigations into whether adequate and appropriate health research is being conducted in conformity with international right-to-health demands: G. Backman et al., “Health Systems and the Right to Health: An Assessment of 194 Countries” (2008) 372 *Lancet* 2047-2085.

⁶¹ A. Kalache & I. Keller, “The Greying World: A Challenge for the Twenty-First Century” (2000) 83 *Science Progress* 33-54.

⁶² European Observatory on the Social Situation, *Demographic Trends, Socio-Economic Impacts and Policy Implications in the European Union – 2007* (Luxembourg: EU Publications Office, 2008).

⁶³ UN, *World Population Prospects: The 2010 Revision* (NY: Department of Economic & Social Affairs, Population Division, 2011). Although we note that the global population has just topped seven billion, having grown by a billion people in just 12 years.

⁶⁴ WHO, *Active Aging: A Policy Framework* (Geneva: WHO, 2002).

⁶⁵ J. Gruber & D. Wise, “An International Perspective on Policies for the Aging Society”, NBER Working paper No. 8103, 2001, available at <http://www.nber.org/papers/w8103>.

⁶⁶ WHO, *Active Aging: A Policy Framework* (Geneva: WHO, 2002), at 17. From a programmes perspective, one can already find discussions about retirement ages and the management and funding of pension schemes into the future: see Editorial, “70 of Bust”, 9-15 April 2011, *Economist*, p. 13, and P.

For example, people are living longer, but they are not necessarily living in good health; they are living longer with chronic diseases and multiple health conditions/ailments,⁶⁷ and they are thus altering disease patterns.⁶⁸ They are placing much greater demands on healthcare systems to offer a range of effective and accessible cures and/or treatments for age-related conditions, including dementia and old-age depression. The pressures faced by geriatric and palliative care wards (in particular) and their need to offer coordinated and integrated short- and long-term care will be enormous and unprecedented.⁶⁹ Simultaneously, a shift in the ‘old-age dependency ratio’ is being prompted; whereas today there are some four working-age people for every pensioned person, this is expected to drop to two by 2050.⁷⁰ In addition to placing increasing pressure on working-age people, this will threaten existing healthcare funding models, and this at a time when healthcare systems are already faltering and collapsing.⁷¹

The above will place increasing pressure on medical research to deliver practical and cost-effective solutions for society’s growing healthcare needs. Concomitantly, it will increase the pressure on research funding bodies and healthcare systems to realise as much value-for-money as possible through that research. Obviously, healthcare systems are important sources and users of new life science knowledge and technologies,⁷² but while research *has* delivered new technologies and treatments to healthcare systems, these have not typically been low-cost innovations capable of timely delivery to large populations, including those in lower-income regions/jurisdictions.⁷³ Currently, health research and technologies often make

Coggan et al., “Pensions – Falling Shorts” , 9-11 April 2011, *Economist*, Special Report. From a systemic perspective, there are concerns about how to accommodate the growing number of geriatric patients. For example, the balance in the provision of elderly care/support as between home-based options and long-term institutional care has shifted toward the latter as higher female employment rates have risen and family mobility has increased. This balance-shift, combined with growing numbers of elderly people will cause acute problems: C. Masseria & E. Mossialos, *Research Note: How Much Care for Older People will be Needed? What can Policies do to Avoid or Reduce Dependency and to Ensure that Adequate Care will be Available?* (Luxembourg: EU Publications Office, 2006). For an assessment of expected care needs in the UK, see D. Wanless, *Securing Good Care for Older People: Taking a Long-Term View* (London: King’s Fund, 2006).

⁶⁷ By 2006, life expectancy in the EU-27 was 82 years for women and 75.8 years for men: European Commission, *The Social Situation in the European Union 2009* (Luxembourg: EU Publications Office, 2010) at 335. Life expectancy in several EU countries, including the UK, is now higher, though discrepancies exist across national borders: D. Leon, “Trends in European Life Expectancy: A Salutory View” (2011) *Int J Epidemiology* 1-7, early online, at <http://ije.oxfordjournals.org/content/early/2011/03/16/ije.dyr061.full.pdf+html>.

⁶⁸ WHO, *Life in the 21st Century: A Vision for All* (Geneva: WHO, 1998).

⁶⁹ WHO Europe, “Conference Document: Health Workforce Policies in the European Region”, Doc. EUR/RC57/9, 30 June 2007, available at http://www.euro.who.int/_data/assets/pdf_file/0020/74540/RC57_edoc09.pdf.

⁷⁰ European Commission, *Europe’s Demographic Future: Facts and Figures on Challenges and Opportunities* (Luxembourg: EU Publications Office, 2007).

⁷¹ WHO, *Everybody’s Business: Strengthening Health Systems to Improve Health Outcomes* (Geneva: WHO, 2007).

⁷² Healthcare systems and health research are both important sources and users of life science knowledge and innovative technologies: European Commission Communication, *Modernising Social Protection for the Development of High-Quality, Accessible and Sustainable Health Care and Long-Term Care: Support for National Strategies Using the ‘Open Method of Coordination’*, COM/2004/0304 Final, available at http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=COMfinal&an_doc=2004&nu_doc=304.

⁷³ Medical technologies include drugs, diagnostic tools, screening devices, and non-drug therapies.

healthcare delivery more expensive:

To date, advancing technology would seem to have pushed up overall spending – i.e. by the introduction of new expensive pharmaceuticals and investments in new systems instruments – rather than saving money.⁷⁴

This is reiterated by the WHO, which reports that, rather than old age per se driving healthcare costs:

... the major causes of escalating healthcare costs are related to ... [i]nefficiencies in care delivery ... payment systems that encourage long hospital stays, excessive numbers of medical interventions, and the inappropriate use of high cost technologies. ... For example, in the United States and other OECD countries, new technologies were sometimes rapidly introduced and used where alternative and less expensive procedures already existed, and for which the marginal effectiveness was relatively low.⁷⁵

This trend cannot be sustained as the number of elderly climb and the number of financial contributors to the research undertaking and to healthcare systems decline.⁷⁶ If it does continue, it could lead to systemic collapse, but before doing so, it would almost certainly make (access to) healthcare highly inequitable (or rather dramatically more inequitable than at present).

If governments take Humphrey's admonition seriously – and they should – then they must consider how to get the most out of health research activities so that those activities contribute in a real and beneficial way to healthcare delivery in a context defined by widespread agedness. They must ensure that new knowledge reaches, is tested, and is ultimately deployed by the most, and most appropriate, people in a timely fashion despite shrinking health system support and research investment. All of this, quite clearly, points to a need to pay much greater attention to effective and efficient data-sharing, which invariably extracts more value from research data and spreads knowledge to wider and more diverse users. Related to the issue of healthcare system operation in an aging context, there is also a need to more effectively share health records across and between systems as elder patients move jurisdictions to be with or closer to family.

Argument 3: Elderly Research Participants Deserve Reciprocity

Whereas the first argument was legal and the second systemic/policy, this third and last age-related argument is moral; it turns on how elderly participation in research

⁷⁴ E. Rynning, *supra*, note 56, at 303. Examples of research-driven innovations that have entered healthcare systems are pre-natal genetic diagnostics and improved fertility treatments, which are highly technical and expensive, and therefore of limited use. It has been noted that recent health and medical improvements, including in life expectancy, have been enjoyed primarily by the socio-economically advantaged, not by the disadvantaged: D. Leon, *supra*, note 67.

⁷⁵ WHO, *Active Aging: A Policy Framework* (Geneva: WHO, 2002), at 42.

⁷⁶ See V. Fuchs, "Health Care for the Elderly: How Much? Who Will Pay for It?" (1999) 18 *Health Affairs* 11-21, who, analysing the US context, reported that if trends to 1995 continue until 2020, healthcare consumption by the elderly will be some US\$25,000 per person (in 1995 dollars) compared with \$9,200 in 1995.

squares with some of the socio-moral values felt to be critical to the life science undertaking and to healthcare more generally. We argue that elder participation in research studies, and thereby their interaction with these values, is such that their contributions can, more than others', be characterised as purely altruistic. On the basis of reciprocity and solidarity, they are owed something for their socially valuable and personally burdensome contribution. One option is to accelerate research outputs through improved data-sharing.

We begin with a consideration of one of the foundational concepts in the research recruitment and donation setting: altruism. Theories of altruism can be found in Chinese, Greek, and Roman philosophies, as well as in the Torah and New Testament.⁷⁷ Without claiming the term itself (which was coined in 1851 by Auguste Comte), Adam Smith captured the meaning of altruism. Emphasising the *quantitative*, he said:

How selfish soever man may be supposed, there are evidently some principles in his nature which interest him in the fortune of others, and render their happiness necessary to him, though he derives nothing from it except the pleasure of seeing it.⁷⁸

Socio-biologists adopt a similarly quantitative description, defining 'altruism' as an act that benefits the actor less than the recipient.⁷⁹ Economists define 'altruistic behaviour' as conduct that could have resulted in better outcomes for the actor had she chosen to ignore the effect of her choice on others.⁸⁰ Game theorists label 'altruists' as individuals who give more weight to others' outcomes than to their own in deciding strategies.⁸¹

Other definitions emphasise the *qualitative*; while not ignoring the cost-benefit balance to the actor, they focus on intentions and motivations. Thus, they suggest that altruistic behaviour must:⁸²

1. benefit a third person;
2. be performed with the intention of such benefit and no other purpose;
3. be performed without expectation of personal reward; and
4. be performed voluntarily and intentionally.

Altruism is thus juxtaposed with egoism, the latter which is a motivational state characterised by a self-oriented aim to increase one's own welfare.⁸³

⁷⁷ A. Midlarsky & E. Kahana, "Altruism, Well-Being and Mental Health in Late Life" in S. Post (ed.), *Altruism and Health: Perspectives from Empirical Research* (Oxford: OUP, 2007) 56-69.

⁷⁸ A. Smith, *The Theory of Moral Sentiments*, 6th ed. (London: A. Millar, 1790), at I.I.1.

⁷⁹ J. Piliavin & HW. Charng, "Altruism: A Review of Recent Theory and Research" (1990) 16 *Ann Rev Sociology* 27-65. Some have gone so far as to describe it as self-destructive behaviour performed for the benefit of others: E. Wilson, *Sociobiology: The New Synthesis* (Cambridge: Harvard U Press, 1975).

⁸⁰ H. Margolis, *Selfishness, Altruism and Rationality* (Cambridge: CUP, 1982).

⁸¹ W. Liebrand, "The Ubiquity of Social Values in Social Dilemmas" in A. Wilke et al. (eds.), *Experimental Social Dilemmas* (Frankfurt: Verlag Peter Lang, 1986) 113-134.

⁸² J. Macaulay & L. Berkowitz (eds.), *Altruism and Helping Behavior* (NY: Academic Press, 1970), D. Bar-Tal, "Altruistic Motivation to Help: Definition, Utility and Operationalisation" (1985-86) 13 *Humboldt J Soc Relations* 3-14, and D. Krebs, "The Challenge of Altruism in Biology and Psychology" in C. Crawford et al. (eds.), *Sociobiology and Psychology* (NJ: Earlbaum, 1987) 81-118.

⁸³ G. Lewes, *Comte's Philosophy of the Sciences* (London: George Bell, 1904), and C. Batson, "Experimental Tests for the Existence of Altruism" in *Philosophy of Science Association* (ed.), *PSA*:

Regardless of the definitional emphasis adopted (quantitative or qualitative), theorists discern two different types of altruism: one is impulsive, spontaneous, reflexive, or unconscious and often directed at kin;⁸⁴ the other is more conscious and considered and in response to perceived social needs and expectations. This latter type captures the idea of ‘generalised altruism’ described by Alexander.⁸⁵ While it has been noted that altruism need not necessarily produce ‘pro-social behaviour’, it can and very often does result in such behaviour.⁸⁶

Modern medical research relies on unpaid human tissue donation and the opening up of personal data to researchers (ie: which relies on altruistically given ‘gifts’⁸⁷), and it involves both altruism typologies being translated into pro-social behaviour. Unsurprisingly (and sadly), pure altruism is a relatively rare phenomenon.⁸⁸ However, elder participation in research – which is now pressing as age-related conditions become more ubiquitous and taxing upon healthcare systems – might be characterised as closer to pure altruism than that of any other group. This is so for at least three reasons:

- First, elder participants often face heavier burdens as a cost of participation. For example, as people become infirm, simple matters of accessing and enduring transportation become significant barriers, and transportation has been identified as a recruitment challenge.⁸⁹ In addition, depending on the study, individuals may be asked to put at risk their already tenuous grip on good health.⁹⁰ Another burden born most heavily by elderly participants is availability of, and access to, services (not just health services) to support them in their activities or assist them if their health is impaired by the study.⁹¹
- Second, because of the length of time it takes to move new knowledge from ‘bench to bedside’, elder participants will not likely see (nor will most *expect* to see) the ultimate fruits of their participation. By comparison, younger participants, rightly or wrongly, will often expect to benefit down the road from the knowledge to which their participation contributes. In short, for many types of research, elder participants will rarely gain any instrumental individual health benefit, and may in fact suffer at least minor net health

Proceedings of the Biennial Meeting of the Philosophy of Science Association (Chicago: PSA, 1992) 69-78.

⁸⁴ Although it is often extended more broadly – to strangers – in emergency situations.

⁸⁵ R. Alexander, *The Biology of Moral Systems* (NY: Aldine, 1987).

⁸⁶ J. Piliavin & HW. Charng, *supra*, note 79, J. Piliavin et al., *Emergency Intervention* (NY: Academic Press, 1981), M. Hoffman, “Is Altruism Part of Human Nature?” (1981) 40 *J Pers Soc Psychol* 121-137, I. Vine, “Sociobiology and Social Psychology: Rivalry or Symbiosis?” (1983) 22 *British J Soc Psychol* 1-11, J. Hill, “Human Altruism and Sociocultural Fitness” (1984) 7 *J Soc Bio Struct* 17-35, N. Eisenberg & P. Miller, “The Relation of Empathy to Prosocial and Related Behaviors” (1987) 101 *Psychol Bull* 91-119, and C. Batson & A. Powell, “Altruism and Prosocial Behavior” in I. Weiner (ed.), *Handbook of Psychology* (UK: Wiley Online, 2003) 463-484.

⁸⁷ R. Titmuss, *The Gift Relationship* (London: Penguin Books, 1973).

⁸⁸ So claimed by C. Batson & A. Powell, *supra*, note 86.

⁸⁹ L. Lovato et al., “Recruitment for Controlled Clinical Trials: Literature Summary and Annotated Bibliography” (1997) 18 *Controlled Clin Trials* 328-357.

⁹⁰ M. Boles et al., “Primary Prevention Studies and the Healthy Elderly: Evaluating Barriers to Recruitment” (2000) 25 *J Community Health* 279-292.

⁹¹ For access issues in the UK, see Department of Health, *National Service Framework for Older People* (London: DoH, 2001) and Department of Health, *National Service Framework for Older People: A Report of Progress and Future Challenges* (London: DoH, 2003).

deficits as a result of contributing.

- Third, elder participants make this contribution to society despite the fact that they, as a group and individually, are marginalised by that society and are thus properly recognised as a ‘vulnerable group’. For example, they often experience institutional, spatial, and cultural age segregation.⁹² This, combined with the onset of disability and the (oft-experienced) reality of subsisting on (low) fixed incomes,⁹³ further marginalises them and impacts negatively on their happiness and social status.⁹⁴ Finally, social roles, which serve to build and maintain connections between individuals, are frequently lost, thereby decreasing wellbeing, and they are not adequately compensated for (or replaced) by social institutions.⁹⁵ On top of all this, they are often accused of failing to make valuable contributions to society,⁹⁶ despite typically outperforming younger demographic groups in pro-social activities.⁹⁷

Despite these burdens, the elderly *do* participate, and they have cited a desire to contribute to science and improve the health of others as motivating factors.⁹⁸ For those who believe in a moral duty to participate, the sense of fulfilment of that duty can be a particularly strong motivator.⁹⁹ This says something about the *quality* of elder participation in research; it suggests that their participation is more virtuous than that of other groups because it costs them more and offers them less in material return. Having said this, we acknowledge that the elderly may experience some intangible but very real benefits from participation: empirical research has demonstrated that helping others promotes personal satisfaction, confidence, self-esteem, and social integration (ie: it improves self-perceptions about quality of life), as well as social (re)integration, which, in turn, contributes to emotional wellbeing.¹⁰⁰

⁹² G. Hagestad, “Should We Be Concerned About Age Segregation?” (2006) 28 *Research on Aging* 638-653.

⁹³ Particularly women over 65 living alone: European Commission, *The Social Situation in the European Union 2009* (Luxembourg: EU Publications Office, 2010), at 6.

⁹⁴ A. Walker, “The Social Creation of Poverty and Dependency in Old Age” (1980) 9 *J Soc Policy* 49-75, and A. Deaton, “Income, Aging, Health and Well-Being Around the World: Evidence from the Gallup World Poll” in D. Wise (ed.) *Research Findings in the Economics of Aging* (Chicago: U Chicago Press, 2010) 235-263.

⁹⁵ P. Thoits & L. Hewitt, “Volunteer Work and Well-Being” (2001) 42 *J Health Soc Behaviour* 115-131.

⁹⁶ Noted by S. Giordano, “Respect for Equality and the Treatment of the Elderly: Declarations of Human Rights and Age-Based Rationing” (2005) 14 *Cambridge Q Healthcare Ethics* 83-92.

⁹⁷ A. Midlarsky & E. Kahana, “Altruism, Well-Being and Mental Health in Late Life” in S. Post (ed.), *Altruism and Health: Perspectives from Empirical Research* (Oxford: OUP, 2007) 56-69.

⁹⁸ E. Schron et al., “Clinical Trial Participant Satisfaction: Survey of SHEP Enrollees” (1997) 45 *J Am Geriatric Soc* 934-938.

⁹⁹ See E. Kahana et al., “Beyond Dependency, Autonomy and Exchange: Pro-social Behaviour in Late Life Adaptation” (1987) 1 *Soc Justice Res* 439-459, and E. Midlarsky & E. Kahana, *Altruism in Later Life* (California: Sage Publications, 1994), who report that a sense of duty often motivates older adults, who are, in fact, more probable to have altruistic motivations than other groups.

¹⁰⁰ See D. LeBlanc, “Case Studying the Philosophy, Integrity and Emotional Health of the Elderly” (1987) 13 *Edu Gerontology* 387-402, R. Cialdini & J. Fultz, “Interpreting the Negative Mood – Helping Literature via ‘Mega’-Analysis: A Contrary View” (1990) 107 *Psychological Bull* 210-214, J. Piliavin & P. Callero, *Giving Blood* (Baltimore: Johns Hopkins U Press, 1991), E. Midlarsky, “Helping as Coping” in M. Clark (ed.), *Review of Personality and Social Psychology* (Cal: Sage, 1991) 238-264, K. Pillemer et al. (eds.), *Social Integration in the Second Half of Life* (Baltimore: Johns Hopkins U Press, 2000), M. Snyder et al., “The Functional Approach to Volunteerism” in R. Maio & J. Olson (eds.), *Why We Evaluate: Functions of Attitudes* (NJ: Erlbaum, 2000) 365-393, and P. Sorokin,

In any event, perhaps in recognition of the fact that pure altruism is so rare, but with a view to maintaining social relationships, some argue that gifts should be met with some reciprocation which both encourages further acts of giving and embodies the spirit of mutual support (solidarity) within a community.¹⁰¹ So while one can accept, reject, or ignore a gift, once accepted, the recipient, who has presumably benefited from the gift, must offer something in return.¹⁰² Importantly, that reciprocation need not go to the original giver. The concept of ‘third-party altruism’ is that the giver does not expect something for themselves, but rather something for a third party; the receiver should reciprocate the gift by conferring rewards on others.¹⁰³ This transforms the gift relationship into a multi-person relationship grounded on social cooperation (solidarity again).

As suggested, this reciprocation implicates and is grounded on the solidarity value. The EU Ministers of Health have identified solidarity as a core value fundamental to health systems, which themselves are integral to Europe’s social infrastructure.¹⁰⁴ They have defined solidarity as being closely linked to the financial and access arrangements relating to national health systems.¹⁰⁵ While they rightly acknowledge the proximity of solidarity to universal access and equality, their definition is overly narrow and wrongly collapses solidarity into financial conditions and other separately articulated values. Though solidarity has many roots and conceptions, the following propositions better capture its socio-moral content:¹⁰⁶

- Solidarity recognises that individuals are naturally and irrevocably embedded in social contexts; they are in a state of interrelationship or interconnectedness with individuals, groups and society. It therefore emphasises community.
- Solidarity is grounded in compassion, fraternity and a genuine interest in the well-being of others, the ultimate goal being to construct, through personal and collective actions, a just/decent and fair society. It therefore emphasises equality and the active promotion of welfare.
- Solidarity demands common action to uphold the complex of social relationships and values that is needed to realise useful standards of decency and justice. It therefore emphasises the role of duties flowing from and toward individuals and communities, and may require collective interests to take priority over the interest of individuals or sub-collectives.

While altruism may move the elderly to act, solidarity demands that we, as a research community and a society, appropriately reciprocate the contributions made by elderly participants. This reciprocation has the effect of completing the act of solidarity begun by the elder participant. It is incumbent on researchers to take the lead in closing this circle. If researchers fail to do so appropriately (or meaningfully), they

The Ways and Power of Love (Penn: J Templeton Foundation Press, 2002).

¹⁰¹ M. Mauss, *The Gift* (Oxford: Routledge, 1990), at 50-54.

¹⁰² A. Komter, *Social Solidarity and the Gift* (Cambridge: CUP, 2005), at 116-117.

¹⁰³ R. Trivers, “The Evolution of Reciprocal Altruism” (1971) 46 *Quart Rev Biology* 35.

¹⁰⁴ Council of the European Union, “Council Conclusions on Common Values and Principles in European Union Health Systems” (2006) Official J EU C146/1-3.

¹⁰⁵ *Ibid*, Annex.

¹⁰⁶ See the discussion in S. Harmon, “Solidarity: A (New) Ethic for Global Health Policy” (2006) 14 *Health Care Analysis* 215-236.

abuse the elder participants' (often costly) altruistic choice by undermining the basis (or one of the bases) upon which the choice was made, which, as noted, is to benefit society through research that will improve the health of others.

How can this circle be closed?

The most obvious and effective way, and the most appreciated by elder participants, who have a unique relationship with the research undertaking, is to generate new knowledge and share it with humanity and with other specialists who can put it to work. Improved data-sharing – data-sharing that is more widely practiced, more efficiently realised, and performed earlier in the research process – is the most valuable and traceable means of meeting our reciprocation responsibilities to elderly participants. Data-sharing is a useful but necessary 'in-pipeline' response because, as noted, elderly participants will not likely see the end product. Their 'higher' or 'purer' altruism, which is becoming more important as work on age-related conditions becomes more pressing, necessitates reciprocating actions (actions which additionally serve to help operationalise their rights as outlined above), and improved data-sharing is an appropriate vehicle for doing so.

CONCLUSIONS

Knowledge is a socio-moral or human value, and therefore the generation of knowledge is a valuable pursuit. If the biosciences are to fulfil their promise of both generating knowledge and translating that knowledge into socially beneficial products and practices, then research data and subsequent findings must be shared widely and rapidly. If support for this practice beyond the scientific were needed, the vulnerable, with the elderly as an example thereof, surely provide that support. As demonstrated above, they do so in three important ways:

1. Argument 1: As rights holders who have (presumably) contributed to society for a longer period than any other group, they are entitled to expect maximum value from research which interacts with and facilitates their health, equality, and elder rights in a variety of ways.
2. Argument 2: As a growing demographic which will inevitably become more demanding of healthcare (thus exerting increased stress on already precarious healthcare systems), they serve as a reason to rethink how those healthcare systems and their feeder research systems work. Their growing prominence as a social group forces us to think more carefully about how we make the transition from bench-to-bedside more efficient.
3. Argument 3: As altruists of a higher order who are additionally more pro-social than other groups, they are owed some real and measurable return on their contributions, particularly in light of their fleeting expectations of actually enjoying new treatments to which they might have contributed.

Again, while all of these propositions/arguments are coloured by morality, they are quite different arguments; one is based in law and legal instruments, one in health systems and how they respond in practice to new pressures, and one in medical/research ethics. Additionally, we do not necessarily see one argument as being more convincing or more weighty than the others; they are equally important and potentially equally compelling. But to help us realise the ideal situation, all three

must feed into the consideration.

But how do we realise the improved data-sharing that the elderly are due? This is a technical question which researchers, research funders, and research policymakers need to address in a holistic way, and in short order.¹⁰⁷ The already existing variety of policies and instruments which aim to entrench core data-sharing practices have not succeeded.

What can be done?

As a start, we might consolidate and rationalise the many (non-binding) statements that exist, taking full stock of where different biomedical research fields are with respect to data-sharing. Funders should adopt and enforce harmonised practices (and standardised practices where appropriate). Ultimately, however, and because a lot of this research is publicly funded (or alternatively relies in no small part on publicly funded research), the law has a valid and important role to play; it should be deployed to facilitate and enforce increased data-sharing in biomedical research. A normative (legal) approach is preferred because it can advance autonomy, encourage solidarity, and reward altruism all at the same time. In doing so, the law can enumerate and enforce best practices for a range of settings (eg: publicly funded research should meet stronger minimum levels of data-sharing; private research should have a legal responsibility to negotiate with participants data-sharing levels above and beyond that, or, if lower, should clearly defend this lower level to participants and Research Ethics Committees).¹⁰⁸ Of course, we must reiterate that our intention is to make the argument for greater and/or improved data-sharing, not to offer a bespoke legal regime for doing so. As should be clear from the above, we see that as a collaborative and international undertaking (but one which would result in a necessarily international legal instrument).

While the metaphors of velocity (ie: inertia, acceleration, speed, races) that are often associated with biomedical research are usually hyperbolic, misplaced, and largely counter-productive,¹⁰⁹ the proper valuing of the elderly (as contributors to society and research to whom respect and duties are owed) demands that we reconsider these metaphors; they do take on a new seriousness. While pace can never be a core objective of good science, the idea of doing science well (ie: doing it effectively and efficiently so that outputs are correct, socially useful, and, importantly, timely) is profoundly appropriate and very much here implicated. We conclude that increased and more effective data-sharing is most appropriate from the perspective of the elderly insofar as it will promote the rapid advancement of knowledge and better distribution of scientific knowledge and benefits, all of which is particularly important to aging populations.

¹⁰⁷ By 'holistic' we mean that stakeholders must take a broad and encompassing or inclusive view of the field and its relevant regulatory components and make changes in a joined-up way, so that alterations at one point are appropriately recognised or carried through at other points.

¹⁰⁸ It is appropriate to separate the two regimes because governments have a duty to promote and realise health under international law, which duty is not imposed on individuals in the same way.

¹⁰⁹ See B. Nerlich et al. (eds.), *Communicating Biological Sciences* (Surrey: Ashgate, 2009).